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SUMMARY OF INTERVIEW AND SUPPLEMENTAL REMARKS

Applicant : Kagan et al.
App. No : 10/698,148
Filed : October 31, 2003
For : APPARATUS AND METHODS FOR
TREATMENT OF MORBID OBESITY
Examiner : Gray, Phillip A
Art Unit : 3767
Conf No. : 2819

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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- ☐ Discrepancies found, Examiner's Amendment to follow.
☐ Record complete and accurate - Interview Record OK

Examiner's Initials: _____

Review Date: _____

Dear Sir:

Pursuant to the Interview Summary of February 24, 2010, Applicants submit this Summary of Interview for recording in the official file, along with supplemental remarks.

Attendees, Date and Type of Interview

The telephonic interview was conducted on February 12, 2010 and attended by Examiner Phillip Gray, Supervisory Patent Examiner Kevin Sirmons, and Applicants' representatives John Grover and Bryan Wahl.

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

Claim 43

Identification of Prior Art Discussed

U.S. Pat. Pub. No. 2004/0039452 A1 to Bessler

U.S. Pat. Pub. No. 2004/0082963 to Gannoe et al.

U.S. Pat. No. 6,254,642 to Taylor

U.S. Pat. No. 5,470,337 to Moss

Proposed Amendments

No proposed amendments were discussed.

Principal Arguments and Other Matters

With regard to the Bessler/Taylor/Moss rejection, Applicants' representatives discussed how one of ordinary skill in the art would have no reason to replace Bessler's nonpenetrating stent attachment with Taylor's penetrating attachment spikes, and further modified by Moss's expandable anchor, and in fact how Bessler's nonpenetrating attachment teaches away from a penetrating attachment as described in Taylor or Moss. Further, Applicants' representative discussed how the combination would not be expected to be successful, as evidenced by the Factual Declaration of Dr. Christopher Thompson submitted November 21, 2008, of record, which provides objective evidence of one of ordinary skill in the art who was familiar with and practiced the art at the time the invention was made. Further, Applicants discussed how the failure of others described in the Thompson Declaration should merit an unexpected result.

With regard to the Gannoe/Taylor/Moss rejection, Applicants' representatives discussed how the combination failed to teach or suggest the claim requirement of not creating a serosal-to-serosal bond, and modifying the reference to remove Gannoe's plication would destroy the purpose of the reference. Furthermore, Applicants' representatives discussed how one of ordinary skill in the art would have no reason to replace Gannoe's attachment plication with Taylor's penetrating attachment spikes, and further modified by Moss's expandable anchor. Moreover, it was discussed further how the combination would not be expected to be successful, as evidenced by the Thompson Declaration of record. Also, Applicants discussed how the failure of others described in the Thompson Declaration should merit an unexpected result.

Applicants' representatives also inquired into whether the Thompson Declaration had been taken into account by the Examiner, as no Office Action to date had mentioned

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consideration thereof. The Examiner remarked that the Thompson Declaration was considered, was deemed unpersuasive as opinion evidence, and suggested supplementing the Declaration with additional factual evidence.

Results of Interview

No agreement was reached; the Examiner and Supervisory Patent Examiner will discuss the case further with the pre-appeal panel, of which a conference request is pending. Applicants thank Examiner Gray and SPE Sirmons for their time and courtesy extended during the interview.

Supplemental Remarks

As a follow-up response for the record to the Examiner's position expressed during the telephone interview and the Examiner's Interview Summary mailed on February 24, 2010 that the Thompson Declaration was not entitled to sufficient weight as mere "opinion evidence," Applicants disagree. The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry. M.P.E.P. § 2143.01 (III), *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). The Examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, etc. See M.P.E.P. § 2143.01 (III), *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693 (Fed. Cir. 1983), *cert denied*, 464 U.S. 1043 (1984). Opinions introduced on the issue of the level of ordinary skill are usually determined by reference to the subjective reaction of persons so skilled, *In re Oelrich*, 579 F.2d 86, 91 (C.C.P.A. 1978); *In re Meng*, 492 F.2d 843, 848-849 (C.C.P.A. 1974), and even assuming for the sake of argument that a *prima facie* case of obviousness has been established, opinion evidence of one of ordinary skill in the art based on information uniquely within their competence bearing on the level of ordinary skill in the art at the time the invention was made can overcome a *prima facie* case of obviousness. See *id.*

Similar to the *Oelrich* and *Meng* cases cited above, in which opinion affidavits of one of ordinary skill in the art regarding the level of skill in the art was considered dispositive in finding that a claimed invention was nonobvious, the Thompson Declaration was also introduced on the

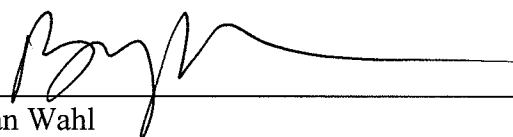
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issue of the level of ordinary skill, and as such should be entitled to considerable weight. Dr. Thompson was a physician in the art at the time the invention was made who has substantial clinical and research experience in gastrointestinal procedures that are the subject of the claimed invention. Thompson Declaration at paras. 1-3. The Thompson Declaration opines on the art cited as a basis for an obviousness rejection by the Examiner based on Dr. Thompson's knowledge, clinical, and research experience that is uniquely within his competence, and clearly states reasons why he would see no reason to combine the cited references to come up with the claimed invention, why he would not have expected the invention to have a reasonable expectation of success, and how the claimed invention produced unexpected results. Thompson Declaration at paras. 7-9. As such, Applicants submit that the Thompson Declaration is compelling evidence of nonobviousness of record on the issue of the level of ordinary skill. *See* M.P.E.P. § 2143.01 (III); *Oelrich*, 579 F.2d at 91; *Meng*, 492 F.2d at 848-849. Thus, Applicants respectfully request that the pre-appeal panel consider and the Examiner reconsider the Declaration in view of the relevant case law and M.P.E.P. sections cited above.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3/24/10

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